PB89-114086

Guidance for the Reregistration of Pesticide Products Containing 4-(2,4-Dichlorophenoxy) Butyric Acid (2,4-DB) and Its Salt Amine and Esters as the Active Ingredient

(U.S.) Environmental Protection Agency
Washington, DC

Sep 88

U.S. Department of Commerce
National Technical Information Service
NTIS

50272-101

REPORT DOCUMENTATION PAGE

1. REPORT NO.

2.

3. Recipient's Accession No. PB89 114086/AS

4. Title and Subtitle
Guidance for the Reregistration of Pesticide Products
Containing 2,4-DP as the Active Ingredient

5. Report Date September 1988

6.

7. Author(s) EPA, Office of Pesticide Programs Registration Div.

8. Performing Organization Rept. No. 540/RS- 88-131

9. Performing Organization Name and Address
U.S. Environmental Protection Agency
Office of Pesticide Programs
Registration Division TS-767C
401 M Street, S.W.
Washington, D.C. 20460

10. Project/Task/Work Unit No.

11. Contract(C) or Grant(G) No.
(C)
(G)

12. Sponsoring Organization Name and Address
Same as #9

13. Type of Report & Period Covered

14.

15. Supplementary Notes

16. Abstract (Limit: 200 words)

This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of date requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

17. Document Analysis a. Descriptors

Pesticides, standards, regulations, manfacturing, chemistry, toxicology, residues, ecology, path of pollutants.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

18. Availability Statement: Publicly Available

19. Security Class (This Report) Unclassified

20. Security Class (This Page) Unclassified

21. No. of Pages 112

22. Price

United States
Environmental Protection
Agency

Office of
Pesticides and Toxic Substances
Washington DC 20460

September 1988
540/RS-88-131

PB89-114086

Pesticides

EPA

Guidance for the Reregistration of Pesticide Products Containing 4-(2,4 -DICHLORO-PHENOXY) BUTYRIC ACID (2,4-DB) as the Active Ingredient

REPRODUCED BY
U.S. DEPARTMENT OF COMMERCE
NATIONAL TECHNICAL INFORMATION SERVICE
SPRINGFIELD, VA. 22161

OMB Control No. 2070-0057
Expires 11/89

GUIDANCE FOR THE

REREGISTRATION OF PESTICIDE PRODUCTS

4-(2,4-DICHLOROPHENOXY)BUTYRIC ACID
(2,4-DB)
AND ITS SALT, AMINE AND ESTERS

AS THE ACTIVE INGREDIENT

CAS REGISTRY NO. 94-82-6

OPP SHAUGHNESSY NO. 030801 (ACID)

EPA CASE NUMBER -- GS-0196

September 1988

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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EPA Form 8580-27	Generic Data Exemption Statement

GLOSSARY OF TERMS AND ABBREVIATIONS

ADI;	Acceptable Daily Intake
a.i.:	active ingredient
CAS:	Chemical Abstract Services (number)
CSF:	Confidential Statement of Formula
EEC:	Estimated Environmental Concentration
EPA:	The U.S. Environmental Protection Agency (Agency)
FIFRA:	The Federal Insecticide, Fungicide, and Rodenticide Act
LC_{50}:	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/l or ppm).
LD_{50}:	Median lethal dose - a statistically derived single dose that can be expected to cause death in 50% of test animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).
LEL:	Lowest Effect Level
MPI:	Maximum Permissible Intake
MRID:	Master Record Identification (number) - EPA's system of tracking studies used in support of registration.
NPDES:	National Pollution Discharge Elimination System
NOEL:	No Observed Effect Level
OPP:	The Office of Pesticide Programs of the U.S. EPA
OES:	The Office of Endangered Species, U.S. Fish and Wildlife Service
PHI:	Preharvest Interval
RfD:	Reference Dose

I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request,[1] focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews and Compendium of Uses may be obtained from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161. Telephone (703) 487-4650.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submittal of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submittal of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICALS COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICALS

This Standard covers 4-(2,4-dichlorophenoxy)butyric acid (2,4-DB) and its inorganic salt, amine and esters.

The acid is not formulated as an end-use product; instead the typical end-use product, as applied, is a formulation of a sodium salt, dimethylamine, or ester (2-butoxyethyl or isooctyl) of the parent compound. With these formulations, the esters or amine may greatly influence the physical characteristics, biological activity and environmental fate of the chemical. The Agency has little or no data to evaluate the behavior of these compounds in the environment. Therefore, the data requirements in this Standard address not only the acid and its inorganic salt but also the amine salt and esters.

Identifying characteristics, codes, and structures are shown below:

Chemical Name: 4-(2,4-dichlorophenoxy)butyric acid
Empirical Formula: $C_{10}H_{10}Cl_2O_3$
Molecular Weight: 249.1
CAS Registry Number: 94-82-6
Shaughnessy Number: 030801

Chemical Name: 2,4-DB, Sodium salt
Empirical Formula: $C_{10}H_9Cl_2NaO_3$
Molecular Weight: 271.13
CAS Registry Number: 10433-59-7
Shaughnessy Number: 030804

Chemical Name: 2,4-DB, Dimethylamine salt
Empirical Formula: $C_{12}H_{17}Cl_2NO_3$
Molecular Weight: 294.23
CAS Registry Number: 2758-42-1
Shaughnessy Number: 030819

Chemical Name: 2,4-DB, 2-butoxyethyl ester
Empirical Formula: $C_{16}H_{22}Cl_2O_4$
Molecular Weight: 349.30
CAS Registry Number: 32357-46-3
Shaughnessy Number: 030853

Chemical Name: 2,4-DB, Butyl ester
Empirical Formula: $C_{14}H_{18}Cl_2O_3$
Molecular Weight: 305.26
CAS Registry Number: 6753-24-8
Shaughnessy Number: 030856

Chemical Name: 2,4-DB, Isooctyl ester
Empirical Formula: $C_{18}H_{26}Cl_2O_3$
Molecular Weight: 361.37
CAS Registry Number: 1320-15-6
Shaughnessy Number: 030863

B. USE PROFILE

Type of Pesticide: Herbicide; Plant Growth Regulator

Pests Controlled: Broadleaf Weeds

Registered Uses: Terrestrial, food

Predominant Uses: Weed control in agricultural crops [alfalfa (16-67% of total usage), soybeans (27-68%), peanuts (5-13%), and clover (less than 2%)]

Mode of Activity: Beta oxidation to 2,4-D acid which stimulates nucleic acid and protein synthesis affecting the activity of enzymes, respiration, and cell division. Broadleaf plants exhibit epinasty, malformed leaves, stems, and roots.

Formulation Types Registered: salt, amine and ester liquids (emulsifiable concentrate, soluble concentrate)

Methods of Application: Aerial and ground equipment

C. BACKGROUND

On December 3, 1986, the Agency issued a preliminary notification of Special Review to registrants of 2,4-DB and 2,4-DP (a similar notice was issued to 2,4-D registrants on September 22, 1986).* This notice was based on epidemiological evidence that indicated an association between farm herbicide use of phenoxy herbicides (including 2,4-D) and cancer (non-Hodgkin's lymphoma). 2,4-DB and 2,4-DP were considered for review at the same time since these compounds are structurally related to 2,4-D.

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*The Special Review process, described in 40 CFR Part 154, is the mechanism by which the Agency determines whether a pesticide poses unresonable adverse effects to man or the environment. In Special Review, the Agency weighs the risk of pesticide use against the benefits of use. Documents are made available during the process to permit public participation in EPA's deliberations prior to any final determination of regulatory action.

The Agency has subsequently issued a proposed decision not to intiate a special review for 2,4-D, 2,4-DB and 2,4-DP (53 FR 9590, March 23, 1988). In this document the Agency proposed that special review is not appropriate at this time for any of the compounds and that a decision regarding whether to group 2,4-D, 2,4-DB and 2,4-DP in future review activities will be made as additional metabolic and toxicologic data are developed. Final action has not been taken on this proposal.

As part of the Agency's strategy on dioxins, the Agency issued a Data Call-In in June 1987 requiring registrants to analyze their 2,4-DB products for certin halogenated dibenzo-p-dioxin or dibenzofuran (HDD and HDF) contaminants. This notice was issued based on the Agency's assumption that, because of the chemical structure, class and certain manufacturing and processing conditions, 2,4-DB products could be contaminated with HDDs or HDFs. Draft protocols for analyzing the pesticide have been submitted. The Agency is evaluating the proposed methods to determine whether they meet the requirements specified in the Data Call-In Notice.

III. AGENCY ASSESSMENT

A. SUMMARY

The Agency has reviewed all data, submitted to support registration of 2,4-DB products, available through November 1987. Based on the review of these data, EPA has reached the conclusions set forth in this Standard. A summary of those conclusions follows. Additional discussion is contained in the remainder of this Chapter.

1. When 2,4-DB is formulated as an ester or amine, the physical characteristics, biological activity and fate in the environment will be affected. EPA has little or no data to evaluate the changed effects resulting from the conversion to an ester or an amine. Therefore, the data requirements imposed by this Standard include testing for the 2,4-DB esters and amine as well as the acid.

2. The Agency has concluded that existing data are inadequate to assess the carcinogenic potential of 2,4-DB. Although under conditions of the study, 2,4-DB was not oncogenic in the rat, in a mouse oncogenic study there was a weak but possible dose-relationship involving hepatocellular carcinomas in males. A new mouse oncogenicity study or historical control data on certain tumor incidence in the strain of mice utilized at the testing facility are required before the significance of these results can be determined.

3. Concern about possible neurotoxic effects for the family of 2,4-D compounds (2,4-D, 2,4-DB, and 2,4-DP) has prompted the requirement for a special neurotoxicity study on 2,4-D. A special study is not required for 2,4-DB at this time. Pending the outcome of the 2,4-D study, however, precautionary labeling requiring gloves is required for all end-use products.

4. Concern about possible groundwater contamination exists for the family of 2,4-D compounds (2,4-D, 2,4-DB, and 2,4-DP). Additional data and a label warning are required.

As a result of this review, the Agency has identified data necessary to further evaluate environmental and human risks associated with the use of 2,4-DB. These data must be submitted in order to maintain registration of products or register new products containing 2,4-DB. These data are listed in the Data Tables contained in Appendix I.

B. TOXICOLOGICAL ASSESSMENT

This section discusses data available to the Agency for 2,4-DB acid and 2,4-DB[x] compounds where [x] refers to the substituted dimethylamine salt, 2-butoxyethanol ester, butyl ester, or isooctyl ester.

1. Acute Toxicity Studies

Acceptable acute oral, acute dermal, primary eye irritation, and primary skin irritation studies indicate that 2,4-DB acid is mildly toxic (Category III and IV). Acute inhalation and skin sensitization testings are data gaps. No data are available for the 2,4-DB[x] compounds.

2. Subchronic Toxicity Studies

An acceptable 90-day study in dogs fed 0, 2.5, 8, 25, or 80 mg/kg/day of 2,4-DB acid showed mortality, body weight depression, and histopathological findings at 25 and 80 mg/kg/day. The lowest-observed effect level (LOEL) was 25 mg/kg/day; the no-observed-effect level (NOEL) was 8 mg/kg/day.

In a rat study, decreases in body weight were seen. The LOEL was 1000 ppm and NOEL 316 ppm. Although this study does not meet Agency requirements, a new study is not required because an acceptable chronic feeding study is available for 2,4-DB acid.

No data are available for 2,4-DB[x] compounds. Data are required for the amine and esters.

3. Chronic Toxicity/Oncogenicity Studies

An acceptable chronic feeding study in CD rats fed 0, 3, 30, or 90 mg/kg/day of 2,4-DB acid showed decreased mean body weight gains, changes in blood chemistry, hematology parameters, and significantly lower heart weights than control at higher dose levels. The LOEL for systemic effects was 30 mg/kg/day and the NOEL was 3 mg/kg/day. Under conditions study 2,4-DB acid was not oncogenic in the rat.

In an oncogenicity study in CD-1 mice fed 0, 3.75, 37.5, and 112.5 mg/kg/day of 2,4-DB acid there was a no conclusive evidence of oncogenicity. However, there was a weak, but possibly dose related increased incidence of hepatocellular carcinomas in males.

This mouse study was deficient because historical control data on certain tumor incidences (bronchiolar adenomas and carcinomas, as well as hepatocellular carcinomas) from males of Crl:CD®1(CR)(BR) mice utilized at the testing facility were not submitted. Unless the data are submitted, the study must be repeated.

Additionally, justification has to be made that the highest dose tested (112.5 mg/kg/day) is a maximum tolerated dose (MTD) (or is close enough to a MTD) in female mice of this strain.

4. Teratology Studies

In a mouse study with 2,4-DB acid the maternal toxicity and fetotoxic NOEL was 60 mg/kg/day, but this study is inadequate because it utilized two dose levels rather than the required three treatment levels.

In a rabbit study with 2,4-DB acid the maternal toxicity NOEL and fetotoxic NOEL was 12 mg/kg/day, but this study is inadequate because it utilized two dose levels rather than the three required and there was an excessive incidence of nonpregnant females.

New teratology studies are required for 2,4-DB acid. No data are available for the 2,4-DB[x] compounds, and teratology studies are required for each ester and amine.

5. Reproduction Studies

In an acceptable two-generation reproduction study in CD rats fed 0, 3, 15, and 75 mg/kg/day of 2,4-DB acid, the reproductive NOEL was 15 mg/kg/day. At 75 mg/kg/day ovarian weight was significantly less in treated dams than in controls, mean birth weights were lower, fewer total pups were born per litter, greater number of pups were dead at birth, and extremely high pup mortality occurred during the lactation period.

6. Mutagenicity Studies

In an Ames study, 2,4-DB acid tested negative with and without metabolic activation. A Chinese Hamster Ovary HGPRT assay suggests that with activation 2,4-DB acid is a weak mutagen immediately below doses causing high levels of cytotoxicity. No evidence of mutagenic activity in this assay was observed without activation, but this part of the assay has been classified as unacceptable because an insufficient level of cytotoxicity was reached. In Chinese Hamster Ovary cells, 2,4-DB acid at 750 and 1000 ug/ml without activation caused a significant increase in chromosomal aberrations with 17.25-hour exposure, but there was no increase in the presence of activation with a 2-hour exposure. In an unscheduled DNA synthesis with rat hepatocytes, there was no evidence of induction.

7. Metabolism Studies

No data are available on the metabolism of 2,4-DB acid or 2,4-DB[x] compounds. Data are required for the acid, amine and ester.

8. Neurotoxicity Studies

Several instances of accidental human poisoning with 2,4-D, resulting in severe neurotoxicity, have been reported. Since 2,4-DB is structurally related to 2,4-D, this concern exists for 2,4-DB compounds as well. No acceptable studies for 2,4-DB are available. A neurotoxicity study has been required 2,4-D. If the 2,4-D study shows neurotoxic effects, studies may be required using 2,4-DB.

C. OTHER SCIENCE FINDINGS

1. Environmental Fate

The Agency has no acceptable data pertinent to the fate of 2,4-DB acid or 2,4-DB[x] compounds.

a. Groundwater

Available data for 2,4-D suggest that chemicals in the 2,4-D family of compounds (2,4-D, 2,4-DB, and 2,4-DP) has the potential to contaminate groundwater. The Agency is requiring data to further assess the mobility of these compounds.

b. Reentry

Based on data available to the Agency, 2,4-DB products do not meet the toxicity criteria specified in 40 CFR 158 for reentry data and the time of application to weeds coupled with rapid dissipation, limits the exposure of workers reentering the area of application. Reentry data are not being required at this time.

c. Pesticide Incident Monitoring System (PIMS)

PIMS files covering the period 1966 to 1979 reported incidents involving drift damage to nontarget plants from aerial (173 reports) and ground (104 reports) application, as well as volatilization (35 reports) for unspecified 2,4-D (family) compounds.

2. Ecological Effects

Available data are insufficient to completely assess the ecological effects of 2,4-DB acid and 2,4-DB[x] compounds to wildlife and aquatic organisms. The following preliminary conclusions can be made, however, based on available data, (NOTE: all figures are LC_{50} values):

a. Avian Effects

No acceptable acute oral data are available on any 2,4-DB compound. The Agency has acceptable dietary studies on 2,4-DB acid and 2,4-DB sodium salt to characterize these compounds as practically nontoxic (> 5000 ppm, respectively) to waterfowl and upland game birds on a subacute basis. There are no avian subacute oral data available for the 2,4-DB[x] compounds, and these data are required.

b. Aquatic Organism Effects

Acceptable data on 2,4-DB acid and 2,4-DB sodium salt indicates these compounds are moderately to slightly toxic to freshwater fish (fathead minnow 18 ppm, bluegill sunfish 7.5 and 17 ppm, rainbow trout 2.0 and 14 ppm, depending on test conditions). There are no acceptable data for acute toxicity to freshwater invertebrates on any 2,4-DB compound. There are no data available on acute toxicity to freshwater fish for the 2,4-DB[x] compounds.

c. Nontarget Insect Effects

Acceptable data on 2,4-DB dimethylamine indicates a low toxicity to bees. Data from a honey bee acute contact study are required for 2,4-DB isooctyl and 2-butoxyethanol esters.

d. Nontarget Plant Effects

There are no data available to evaluate phytotoxicity of 2,4-DB compounds to nontarget plants. Since 2,4-DB is a broadleaf herbicide, there is a potential hazard to nontarget plants from existing uses.

e. Endangered Species

Because of limited environmental fate and ecological effects data, hazard assessments for endangered species cannot be completed at this time. When additional data are received, the Agency will determine whether consultation with the Office of Endangered Species (OES), U.S. Fish and Wildlife Service is appropriate.

3. Product Chemistry

The Agency has noted that 2,4-DB may be contaminated with tetra- through heptahalognated dibenzo-p-dioxins or dibenzofurans, or N-nitrosamines. Certain polyhalognated dibenzo-p-dioxin or dibenzofuran congeners have found to be mutagenic, oncogenic, teratogenic and to cause reproductive toxicity. Nitrosamines have been found to be oncogenic. Analytical data to identify and quantify tetra- through heptachlorrinated dibenzo-p-dioxin or dibenzofuran contaminants were required in a Data Call-In Notice issued in June 1987. Analytic data to identify and quantify N-nitrosamine are being required, as specified in the data tables.

D. TOLERANCE ASSESSMENT

Tolerances of 0.2 ppm have been established for residues of 2,4-DB and its metabolite 2,4-D in or on alfalfa, clover, mint hay, peanuts, soybeans, soybeans hay, and birdsfoot trefoil (40 CFR 180.331). No Mexican tolerance or Codex MRL exists for residues of 2,4-DB. Therefore, no compatibility question exists with respect with Codex MRL.

EPA has evaluated the residue and toxicology data supporting these tolerances. The following issues were considered during this evaluation:

- Whether the current tolerances and food additive regulations are sufficient to cover the actual residues resulting from the use (including FIFRA section 24(c) and intrastate uses).
- Whether group tolerances can be established in accordance with 40 CFR 180.34(f).
- Whether, in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary.
- Whether the tolerances are expressed accurately and in current terminology.

The regulatory results of the Agency's review are set out in the Regulatory Positions and Rationale section.

1. Residue Data

The residue data reviewed in support of these tolerances include the following:

a. Data on the nature of the residues in both plants and animals, including identification of major metabolites and degradates of 2,4-DB. The nature of the residue is not adequately understood.

b. Analytical methodology for determining the levels of residues of 2,4-DB in plants and animals. The nature of the residue in plants and animals has not been adequately described. Therefore, the adequacy of available analytical methods cannot be determined.

c. Storage stability data. These data demonstrate that residues of 2,4-DB and 2,4-D are relatively stable in soybeans, peanuts, and alfalfa for up to 1 year when stored at -20 °C. Additional data are required.

d. Data on the magnitude and levels of residues of 2,4-DB in individual raw agricultural commodities. Data are not adequate to support the established tolerances.

2. Toxicology Data

The toxicology data for 2,4-DB are insufficient to determine an Acceptable Daily Intake (ADI). However, a Provisional Acceptable Daily Intake (PADI) has been calculated based on a rat chronic feeding study with a NOEL of 3 mg/kg/day and using an uncertainty factor of 300. The PADI with a 300-fold safety factor is calculated to be 0.01 mg/kg/day. A comparison of the published tolerances to the PADI was conducted using the Tolerance Assessment System, Routine Chronic Analysis. Based on the analysis a Theortical Maximum Residue Contribution (TMRC) for the U.S. population was calculated to be 0.000083 mg/kg/day, which utilizes 0.83 percent of the PADI. Using the TMRC provides a conservative estimate since it does not consider the effect of processing on residue levels in the raw agricultural commodity, that actual residue levels may be lower than the established tolerance, and that less than 100 percent of the crop is treated.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of available data on 2,4-DB, the Agency has made the following determinations. Where label revisions are imposed, specific language is set forth in the Labeling portion of this section.

1. The Agency will not place 2,4-DB in Special Review at this time.

Rationale. In December 1986, the Agency issued a preliminary notification of special review to the registrants of 2,4-DB and 2,4-DP, based on epidemiologic evidencce available at that time (a similar notice had been issued to 2,4-D registrants in September 1986). After additional evaluation of this evidence the Agency subsequently concluded that these data were inadequate to assess oncogenic potential for the 2,4-D family of compounds (2,4-D, 2.4-DB and 2,4-DP). Therefore, in March 1988, EPA proposed not to initiate a special review of any of the chemicals at this time.

The Agency's concerns regarding toxicological effects have not been fully resolved. Additional epidemiological studies are expected to be completed soon and additional laboratory studies are required by this Standard. As these data become available, the Agency will further evaluate potential risks from these compounds and could initiate a special review at a later time and/or consider additional regulatory action, if appropriate. A decision whether to group 2,4-D, 2,4-DB and 2,4-DP in future review activities will be made as additional metabolic and toxicologic data are developed.

2. The Agency will not restrict the use of 2,4-DB products to certified applicators.

Rationale. Based on available data, 2,4-DB products have not met or exceeded any criteria specified in 40 CFR 152.170 which would indicate a need to restrict the use of 2,4-DB to certified applicators only.

3. The Agency will require data on the amines and esters of 2,4-DB as well as the acid.

Rationale. When 2,4-DB is formulated as an amine or ester, the biological activity and fate in the environment will be affected. Since the Agency has little or no data to evaluate the effects of the [x] moiety, data are needed on each [x] compound to evaluate these characteristics for the particular amine or ester form.

4. The Agency will not establish tolerances for significant new food uses of 2,4-DB.

Rationale. The current residue chemistry and toxicology data are not sufficient to assess existing and pending tolerances. Therefore, the Agency will not consider any significant new food uses until data are available to resolve these issues.

5. The Agency will propose the following technical changes in listing of 2,4-DB tolerances (i) the commodity entry "alfalfa" will be amended to "alfalfa forage" and "alfalfa hay"; (ii) the commodity entry "birdsfoot trefoil" will be amended to "birdsfoot trefoil forage" and "birdsfoot trefoil hay"; and (iii) the commodity entry "clover" will be amended to "clover forage" and "clover hay."

Rationale. These technical changes are required because the addition of "forage" and "hay" clarifies the tolerance statements.

6. The Agency will revise the tolerance statement to include 2,4-DB sodium salt, 2,4-DB dimethylamine salt, 2,4-DB 2-butoxyethanol ester, and 2,4-DB isooctyl ester; if the registrants propose to maintain the use of these 2,4-DB[x] compounds, and provide data to support the tolerances for these salt, amine and esters.

Rationale. The registered uses for 2,4-DB are for the 2,4-DB[x] compounds and they must be a part of the tolerance statement.

7. The Agency will require that registration be proposed for use on mint and appropriate supporting data be submitted or the Agency will revoke the tolerance of 0.2 ppm for residues of 2,4-DB in or on mint hay. Registrants will have three months to notify the Agency of which option they choose.

Rationale. There is no registered use for mint. Therefore, this tolerance is unnecessary if registration is not proposed and supporting data not submitted.

8. The Agency is requiring a groundwater warning statement on the labels of 2,4-DB products.

Rationale. Although available data for phenoxy herbicides suggest that the 2,4-D family of compounds may be mobile in many soil types, and has the potential to contaminate groundwater, its potential to contaminate groundwater is limited by its rapid rate of degradation and uptake by target plants. However, residues of phenoxy herbicides have been detected in groundwater, mostly from point sources, such as mixing, loading and disposal. Since the phenoxy herbicides could be a potential groundwater contaminant, a label statement will advise users to exercise caution when handling phenoxy herbicide products to prevent such contamination.

The Agency is currently finalizing its Agricultural Chemicals in Groundwater Strategy and its policy for restricting the use of pesticide products which may reach groundwater. When the policies are in place, the Agency will consider what action is appropriate for phenoxy herbicide products and other products containing ingredients which may reach groundwater.

9. The Agency is requiring the use of gloves when mixing, loading or applying 2,4-DB products.

Rationale. The major route of exposure to workers handling 2,4-DB is dermal. Use of gloves will mitigate potential hazards involving dermal exposure.

10. The Agency is not requiring a reentry interval for 2,4-DB products.

Rationale. Based on data available to the Agency, 2,4-DB products are of low toxicity and the time of the application coupled with dissipation limits the exposure of workers reentering the area of application. There are no reentry concerns with this chemical at the present time.

11. The Agency is requiring analytical chemistry for 2,4-DB products to evaluate contamination with tetra- through heptahalognated dibenzo-p-dioxins or dibenzofurans, and N-nitrosamines.

Rationale. Polyhalogenated dibenzo-p-dioxins or dibenzofurans may be formed during manufacture of 2,4-DB, and N-nitrosamines may be formed during the manufacture or storage of products containing 2,4-DB amines. The Agency does not have sufficient data to determine the extent or significance of the contamination.

12. The Agency will immediately review certain data as they are submitted.

Rationale. Because of concerns regarding potential risks from 2,4-DB use, the Agency believes it is essential that the following data be reviewed as they are received: all toxicological studies; dioxin, furan and nitrosamine analysis; octanol/ water partition coefficient; vapor pressure; leaching and adsorption/desorption; spray drift; plant and animal metabolism studies and validation methods; and freshwater fish and invertebrate acute toxicity studies.

13. While data gaps are being filled, currently registered manufacturing-use products and end-use products containing 2,4-DB may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. However, significant new uses will not be registered. Registrants must provide or agree to develop additional data, as specified in the data tables, in order to maintain existing registrations.

Rationale. Under FIFRA, the Agency may elect not to cancel or withhold registration even though data are missing or inadequate [FIFRA sections 3(c)(2)(B) and 3(c)(7)]. Issuance of this Standard provides a mechanims for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary. Because of the quantity of data required to maintain existing registrations, the Agency has elected not to consider registration of significant new food uses while data gaps are being filled and data evaluated.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, manufacturing-use products (MPs) and end-use products (EPs) must contain 2,4-DB acid or 2,4-DB[x] compounds, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this document.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To conform to this Standard, MPs and EPs must contain 2,4-DB acid or 2,4-DB[x] compounds. Each formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of active and inert ingredients present in the product as well as impurities.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade, MPs, or EPs containing 2,4-DB acid or 2,4-DB[x] compounds, provided the products are supported by appropriate acute toxicity data and the labeling for the product bears appropriate precautionary statements for the toxicity category in which the product is placed.

3. Use Patterns

To be registered under this Standard, MPs must be labeled for formulation into other MPs or into EPs bearing federally-registered uses. The use index (EPA Compendium of Acceptable Uses) lists all federally-registered uses of 2.4-DB acid and 2,4-DB[x] compounds, as well as approved maximum application rates and frequencies.

The use patterns currently registered are terrestrial food.

D. LABELING

All products must bear appropriate labeling as specified in 40 CFR 156.10, PR Notices 83-2, 83-3, and 87-1, and below. Appendix II contains further information on label requirements.

1. Timeframes for Compliance

Pesticide products containing 2,4-DB acid or 2,4-DB[x] compounds may not be released for shipment by the registrant after October 1, 1989 unless the product bears amended labeling that complies with the requirements of FIFRA, as set forth in this Registration Standard.

Pesticide products containing 2,4-DB acid or 2,4-DB[x] compounds may not be distributed or sold by any person after October 1, 1990 unless the product bears amended labeling that complies with the requirements of this Standard.

In addition to the labeling requirements above, the following must appear on the labeling of all MPs and EPs.

2. Ingredient Statement

The ingredient statement for 2,4-DB products must list the active ingredient as:

4-(2,4-dichlorophenoxy)butyric acid . . . . ____%

or

4-(2,4-dichlorophenoxy)butyric acid,
(salt, amine or ester) . . . . ____%

4-(2,4-dichlorophenoxy)butyric acid
equivalent . . . . ____%

3. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

4. Precautionary Statement

a. Environmental Hazards

1) Manufacturing-use products: "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or waters unless this product is specifically identified and adressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board of Regional Office of EPA."

2) End-use products: "Do not apply directly to water or wetlands (swamps, bogs, marshes, or potholes). Do not contaminate water when disposing of equipment washwaters."

b. Groundwater Advisory (end-use products)

"This product can reach groundwater as a result of mixing and loading. To minimize groundwater contamination from spills during mixing, loading and cleaning of equipment, take the following steps:

Mixing and Loading: When mixing, loading or applying this product, wear chemical resistant gloves. Wash nondisposable gloves throughly with soap and water before removing.

The mixing and loading of spray mixtures into the spray equipment must be carried out on an impervious pad (i.e., concrete slab, plastic sheeting) large enough to catch any spilled material. If spills occur, contain the spill by using an absorbent material (e.g, sand, earth or synthetic absorbent). Dispose of the contaminated absorbent material by placing in a plastic bag and following disposal instructions on this label.

Triple rinse empty containers and add rinsate to the mixing tank.

Cleaning of Equipment: When cleaning equipment, do not pour the wahwater on the ground; spray or drain over a large area away from wills and other water sources."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

   1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

   2. The data requirements listed in Tables A and B.[2]

   3. The labeling requirements specified for manufacturing use products in Section IV.

   4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

   1. The data requirements listed in Table A.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end-use products at this time. Therefore, most Registration Standards do not contain a Table C.

2. The labeling requirements specified for manufacturing use products in Section IV.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption,[3] the data requirements listed in Table C.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person

who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

[Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec.

3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the time-frames for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing

stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6. (cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs
OPP Mailroom (TS-767C)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

Attn: 2,4-DB Registration Standard

All submittals in response to this Registration Standard are non-fee items, including 90-day responses, protocols and waiver requests, data, and revised labeling. Submittals must be clearly identified as being in response to the Registration Standard. Under no circumstances may Registration Standard responses be combined with other types of filings for which fees are required.

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

   a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

   b. Confidential Statement of Formula (EPA Form 8570-4).

   c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

   a. Application for Pesticide Registration (EPA Form 8570-1).

   b. Two copies of any required product-specific data (See Table B).

   c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

   d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

a. Generic data exemption Statement (EPA Form 85[illegible]0-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

> Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.
>
> Table B contains product-specific data requirements that apply only to a manufacturing use product.
>
> Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Prot Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure Active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry

H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column e indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 6 requires that data be submitted, this column indicates when

the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

Table A

Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds[1]

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation[2]	Must Additional Data Be Submitted?	Timeframe for Submission
Subpart C Product Chemistry					
Product Identity					
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No	N/A	Yes[3]	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	No	N/A	Yes[4]	6 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis	TGAI	No	N/A	Yes[5]	12 Months
Physical and Chemical Characteristics					
63-2 - Color	TGAI	No	N/A	Yes[6]	6 Months
63-3 - Physical State	TGAI	No	N/A	Yes[6]	6 Months
63-4 - Odor	TGAI	No	N/A	Yes[6]	6 Months
63-5 - Melting Point	TGAI	No	N/A	Yes[6,7]	6 Months
63-6 - Boiling Point	TGAI	No	N/A	Yes[6,8]	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No	N/A	Yes[6]	6 Months
63-8 - Solubility	TGAI or PAI	No	N/A	Yes[6]	6 Months

Table A

Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds[1] (cont'd)

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation[2]	Must Additional Data Be Submitted?	Timeframe for Submission
§158.190 Product Chemistry					
Physical and Chemical Characteristics (cont'd)					
63-9 - Vapor Pressure	TGAI or PAI	No	N/A	Yes[6]	6 Months
63-10 - Dissociation Constant	TGAI or PAI	No	N/A	Yes[6]	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	No	N/A	Yes[6,9]	6 Months
63-12 - pH	TGAI	No	N/A	Yes[6,10]	6 Months
63-13 - Stability	TGAI	No	N/A	Yes[6]	6 Months
Other Requirements:					
64-1 - Submittal of Samples	N/A	N/A	N/A	No	

1/Requirements apply to 2,4-DB Acid as well as to the sodium salt, dimethylamine, 2-butoxyethyl ester, butyl ester, and isooctyl ester forms, where [x] refers to the substituted salt, amine or ester.

2/Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

Table A
Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds1/ (cont'd)

§158.190 Product Chemistry Footnotes (cont'd)

3/Complete information must be provided regarding the nature of the process (batch or continuous); the relative amounts of beginning materials and the order in which they are added; the chemical equations for each intended reaction; equipment used to produce each intermediate and the final product; reaction conditions; the duration of each step of the process; purification procedures; and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials. In order to assess the potential for contamination with halogenated dibenzo-p-dioxins and dibenzo furans, the description of the manufacturing process must also include the range of temperature conditions, pressure, and pH at each reaction step. Refer to the data requirements set forth in the Agency's June 1987 Data Call-In Notice for analytical chemistry data on halogenated dibenzo-p-dioxins/dibenzofurans in 2,4-DB. These data are due as specified in the Data Call-In Notice.

4/A detailed discussion of all impurities that are or may be present at 0.1% based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. This discussion must also address the possible formation of dibenzo-p-dioxins and dibenzo furans for all products and N-nitrosamines for amines. Refer to the data requirements set forth in the Agency's June 1987 Data Call-In Notice for analytical chemistry on halognated dibenzo-p-dioxins/dibenzofurans in 2,4-DB. These data are due as specified in the Data Call-In Notice.

5/Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used.

6/Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

7/Data required if the technical chemical is a solid at room temperature.

8/Data required if the technical product is a liquid at room temperature.

9/Data required if the technical product is organic and nonpolar.

10/Data required if the test substance is dispersible in water.

Table A

Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds[1/]

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2/]
§158.240 Residue Chemistry					
171-4 - Nature of Residue (metabolism)					
- Plants	PAIRA	Partially	00004685, 00116018	Yes[3/]	18 Months
- Livestock	PAIRA and plant metabolites	No		Yes[4,5/]	18 Months
171-4 - Residue Analytical Methods	TGAI and metabolites	Partially	00004718 00018284 00037371 00046125 00087925 00102943 00115135 00116018 00132034 00161196	Yes[6,7/]	15 Months
171-4 - Storage Stability	TEP and metabolites	Partially	00116018 00132034	Yes[8/]	15 Months

Table A
Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds1/ (cont'd)

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission2/
§158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants					
- Legume Vegetables					
- Soybeans	TEP	Partially	00018284 00037371 00106319 00115135 00116018	Yes9/	18 Months
- Processed Soybean Commodities				Yes10/	24 Months
- Foliage of Legume Vegetables					
- Soybean forage and Hay	TEP	Partially	00037371 00087925 00116018	Yes11/	18 Months
- Nongrass Animal Feeds					
- Alfalfa	TEP	Partially	00061012 00116018	Yes12,13/	18 Months
- Clover	TEP	Partially	00061012 00132034	Yes14/	18 Months
- Trefoil	TEP	Partially	00061012 00116018	Yes15/	18 Months

Table A

Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds[1/] (cont'd)

Data Requirement	Test Substance	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[2/]
§158.240 Residue Chemistry					
171-4 - Magnitude of the Residue in Plants (cont'd)					
- Miscellaneous Commodities					
- Mint	TEP	Partially	00102943	Yes[16/]	18 Months
- Peanuts	TEP	Partially	00161196	Yes[17/]	18 Months
- Processed Peanut Products			00116018	Yes[18/]	24 Months
171-4 - Magnitude of Residue in Meat/Milk/Poultry/Eggs	TGAI or plant metabolites	Partially	00004701 00027041 00116018	Reserved[19]	

1/Requirements apply to 2,4-DB Acid as well as to the sodium salt, dimethylamine, 2-butoxyethyl ester, butyl ester, and isooctyl ester forms, where [x] refers to the substituted salt, amine or ester.

2/For Magnitude of the Residues in Crops, the timeframes for submitting data are 18 or 24 months, as appropriate commencing with the 1989 planting season.

3/Data depicting the distribution and metabolism of ring-labeled [^{14}C]2,4-DB in or on alfalfa, soybeans (mature seed and forage), and an oilseed crop. If metabolism is not similar in these three crops, additional studies using other crops may be required. A completely characterized test substance representative of technical 2,4-DB (including impurities) used in commercial formulations must be applied foliarly at rates sufficiently high to permit characterization of ^{14}C-residues. Sample intervals must include the day of application and the identities and quantities of residues in or on mature plant parts must be determined in order to elucidate terminal residues. Representative samples must also be analyzed by proposed and/or existing enforcement methods to ascertain that all residues of concern are determined.

4/Metabolism studies using ruminants and poultry must be submitted. Animals must be dosed for at least 3 days with ring-labeled [^{14}C]2,4-DB (acid) at a level high enough to permit quantification of the ^{14}C-residues. If necessary hydrolysis and reextraction of samples and aqueous fractions must be applied to release any ^{14}C-conjugates. Milk and eggs must be collected within 24 hours of the final dose. The distribution and characterization of residues must

Table A
Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds1/ (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

be determined in milk, eggs, liver, kidney, muscle, and fat. Samples from these studies must also be analyzed using all current and proposed enforcement methods to ascertain that the methods are capable of adequately recovering and quantifying all residues of toxicologic concern. [If the required plant metabolism studies using a radiolabeled dimethylamine salt of 2,4-DB reveal that dimethylamine, per se, and/or the dimethylamine salt will occur as a residue in or on alfalfa, birdsfoot trefoil, clover, mint, peanuts, soybeans, and soybean hay, metabolism studies in ruminants and poultry are also required using [^{14}C]dimethylamine or the [^{14}C]dimethylamine salt.]

5/Data depicting the nature of 2,4-DB residues in swine are also required if the required metabolism studies with ruminants and poultry reveal that the metabolism of 2,4-DB in these animals differs from that in rats.

6/A PAM Vol. I, Section 222 multiresidue protocol for the determination of chlorophenoxy acids and esters is currently employed for enforcement purposes and will suffice for the testing of 2,4-DB per se under the PAM I protocols I-IV [40 CFR 158.240(b)(15)].

7/If the required animal metabolism data reveal metabolites of concern, analytical methods for data collection and tolerance enforcement (including multiresidue procedures) will be required.

8/All residue data requested in this Standard must be accompanied by sample storage data (storage conditions and time stored) and data depicting the stability of residues under the conditions and for the time intervals specified.

9/Data depicting 2,4-DB residues of concern in or on soybeans harvested 60 days after a single postemergence broadcast application with the soluble concentrate liquid (SC/L) sodium (Na) salt of 0.05 lb ai/A and the emulsifiable concentrate (EC) dimethylamine (DMA) salt at 0.06 lb ai/A. Each formulation must be applied in 5 gallons of water using aerial equipment (in separate tests). Tests must be conducted in IL (16%), IN (8%), IA (14%), and MN (9%) or OH (7%) since these States collectively produced ca. 50% of the 1984 U.S. soybean crop and represent the major U.S. soybean production regions.

10/If no detectable residues of 2,4-DB are observed at a 5X application rate, no processing study is required. If howev the needed data indicate that measurable, weathered residues occur in soybeans, a processing study must be submitted depicting 2,4-DB residues of concern in the processed commodities meal, hulls, soapstock, crude oil, and refined oil, and the milling dust from soybeans.

11/Data depicting 2,4-DB residues of concern in or on soybeans harvested 60 days after a single postemergence broadcast application with the SC/L Na salt of 0.05 lb ai/A and the EC DMA salt at 0.06 lb ai/A. Each formulation must be applied in 5 gallons of water using aerial equipment (in separate tests). Tests must be conducted in IL (16%), IN (8%), IA (14%), and MN (9%) or OH (7%) since these States collectively produced ca. 50% of the 1984 U.S. soybean crop and represent the major U.S. soybean production regions.

12/Data depicting 2,4-DB residues of concern in or on forage and hay of established alfalfa harvested 30 days following aerial application of an EC formulation of the dimethylamine salt at 1.5 lb ae/A and the 2 lb ae/gal EC formulation of the isooctyl ester at 1.0 lb ae/A each in a separate test. The tests must be conducted in CA (8%), CO (3%), or NE (6%); IA (7%), IL (4%), or KS (5%); MI (6%), MN (7%), SD (4%) or WI (12%), and NY (3%), OH (3%), or PA (3%) which collectively accounted for ca. 70% of the 1985 U.S. production of alfalfa.

Table A

Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds1/ (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

13/Data depicting 2,4-DB residues of concern in or on forage and hay of seedling alfalfa harvested 60 days following aerial application of an EC formulation of the dimethylamine salt at 1.5 lb ae/A and the 2 lb ae/gal EC formulation of the butoxyethanol ester at 1.0 lb ae/A each in a separate test. The tests must be conducted in CA (8%), CO (3%), or NE (6%); IA (7%), IL (4%), or KS (5%); MI (6%), MN (7%), SD (4%) or WI (12%), and NY (3%), OH (3%), or PA (3%) which collectively accounted for ca. 70% of the 1985 U.S. production of alfalfa.

14/Data depicting 2,4-DB residues of concern in or on forage and hay of clover harvested 60 days following a single postemergence broadcast application of an EC DMA salt formulation at 1.5 lb ae/A and the 2 lb ae/gal EC isooctyl ester formulation at 1 lb ae/A. Each formulation must be applied in 5 gallons of water using aerial equipment (in separate tests). Tests must be conducted in CA (99% ladino clover), IL (11% red clover) or MO (11% red clover), and OR (29% alsike clover) because these States represent the major regions of 1982 U.S. clover acreage.

15/Data required for alfalfa will be translated to birdsfoot trefoil. Refer to footnotes 13 and 14 for details of data requirements.

16/Data reflecting 2,4-DB residues of concern in or on mint hay harvested at the minimum interval between application and harvest (ca. 60 days) following a single postemergence application of the 1.75 lb/gal EC DMA salt and the 2 lb/gal EC isooctyl ester formulations at 1 lb ae/A in separate tests. Tests must be conducted in OR and WA since these States produced 74% of the 1985 U.S. mint (spearmint and peppermint) grown for oil.

17/Data 2,4-DB residues of concern in or on peanuts harvested 30 days following the last of two applications of an EC formulation of the 2,4-DB dimethylamine salt (030819) at 0.4 lb ae/A. Test must be conducted in AL (36%)/FL (5%)/GA (13%) and NC (28%)/VA (18%), States which collectively account for ca. 100% of 1985 commercial peanut production, excluding product in NM, OK, and TX.

18/Data depicting 2,4-DB residues of concern in meal, crude and refined oil, and soapstock processed from peanuts bearing measurable weathered residues. If residues concentrate in any of these processed commodities, then appropriate food/feed additive tolerance must be proposed.

19/Following receipt and evaluation of the required plant and animal metabolism data and residue data for soybeans and nongrass animal feeds, specific data requirements for livestock feeding studies will be established.

Table A
Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds[1]

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.290 Environmental Fate						
Degradation Studies - Lab						
161-1 - Hydrolysis	TGAI or PAIRA	A	No		Yes	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	A	No		Yes	9 Months
161-3 - On Soil	TGAI or PAIRA	A	No		Yes	9 Months
161-4 - In Air	TGAI or PAIRA	A	No		Yes	9 Months
Metabolism Studies - Lab						
162-1 - Aerobic Soil	TGAI or PAIRA	A	No		Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA		No		No[2]	
163-4 - Aerobic Aquatic	TGAI or PAIRA		No		No[2]	
Mobility Studies						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	A	No		Yes	12 Months
163-2 - Volatility (Lab)	TEP	A	No		Yes	12 Months
164-3 - Volatility (Field)	TEP	A	No		Yes	15 Months

Table A
Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds1/ (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.290 Environmental Fate						
Dissipation Studies - Field						
164-1 - Soil	TEP	A	No		Yes	27 Months
164-2 - Aquatic (Sediment)	TEP		No		No2/	
164-3 - Forestry	TEP		No		No3/	
164-4 - Combination and Tank Mixes	TEP		No		No4/	
165-5 - Soil, Long-Term	TEP	A	No		Reserved5/	
Accumulation Studies						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No		Reserved6/	
165-3 - Irrigated Crops	TEP		No		No7/	
165-4 - In Fish	TGAI or PAIRA	A	No		Yes	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP		No		No7/	

Table A
Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds1/ (cont'd)

§158.290 Environmental Fate Footnotes

1/Requirements apply to 2,4-DB Acid and the dimethylamine salt, 2-butoxyethyl ester, butyl ester and isooctyl ester forms, where [x] refers to the substituted amine or ester. The sodium salt is considered equivalent to the acid.
2/2,4-DB [x] products have no registered aquatic or aquatic impact uses, therefore, no aquatic data are required.
3/2,4-DB [x] products have no registered forestry uses, therefore, no forestry data are required.
4/Tank mix data requirements are not being imposed by this Standard.
5/Soil long-term study is reserved pending results of an acceptable field dissipation study.
6/The rotational crop field study is reserved pending the results of an acceptable confined rotational crop study.
7/Data are not required to support current registered uses or are otherwise not applicable to this standard.

Table A
Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds[1]

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.340 Toxicology					
Acute Testing					
81-1 - Acute Oral Toxicity - Rat	Acid TGAI	Yes	00092159 00128854	No	
	Salt TGAI	No		Yes	9 Months
	Amine TGAI	No		Yes	9 Months
	Esters TGAI	No		Yes	9 Months
81-2 - Acute Dermal Toxicity	Acid TGAI	Yes	00128854	No	
	Salt TGAI	No		Yes	9 Months
	Amine TGAI	No		Yes	9 Months
	Esters TGAI	No		Yes	9 Months
81-3 - Acute Inhalation Toxicity - Rat	Acid TGAI	No		Yes	9 Months
	Amine TGAI	No		Yes	9 Months
	Esters TGAI	No		Yes	9 Months
81-7 - Acute Delayed Neurotoxicity - Hen	Acid TGAI	No		No[2]	
	Amine TGAI	No		No[2]	
	Esters TGAI	No		No[2]	
Subchronic Testing					
82-1 - 90-Day Feeding					
- Rodent	Acid TGAI	No		No[3]	
	Amine TGAI	No		Yes	15 Months
	Esters TGAI	No		Yes	15 Months

Table A
Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds[1]

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
82-1 - 90 Day Feeding (cont'd)					
- Nonrodent (Dog)	Acid TGAI	Yes	00104739	No	
	Amine TGAI	No		Yes	18 Months
	Esters TGAI	No		Yes	18 Months
82-2 - 21-Day Dermal	Acid TGAI	No		Yes	12 Months
	Amine TGAI	No		Yes	12 Months
	Esters TGAI	No		Yes	12 Months
82-3 - 90-Day Dermal	Acid TGAI	No		No[4]	
	Amine TGAI	No		No[4]	
	Esters TGAI	No		No[4]	
82-4 - 90-Day Inhalation	Acid TGAI	No		No[4]	
	Amine TGAI	No		No[4]	
	Esters TGAI	No		No[4]	
82-5 - 90-Day Neurotoxicity	Acid TGAI	No		No[5]	
	Amine TGAI	No		No[5]	
	Esters TGAI	No		No[5]	

Table A
Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds[1] (cont'd)

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.340 Toxicology					
Chronic Testing					
83-1 - Chronic Toxicity (2 Species)					
- Rodent	Acid TGAI	Yes	40257501	No	
	Amine TGAI	No		Reserved[6]	
	Esters TGAI	No		Reserved[6]	
- Nonrodent (Dog)	Acid TGAI	No		Yes	50 Months
	Amine TGAI	No		Reserved[6]	
	Esters TGAI	No		Reserved[6]	
83-2 - Oncogenicity Study (2 Species)					
- Rat (preferred)	Acid TGAI	Yes	40257501	No	
	Amine TGAI	No		Reserved[6]	
	Esters TGAI	No		Reserved[6]	
- Mouse (preferred)	Acid TGAI	No		Yes[7]	6 Months
	Amine TGAI	No		Reserved[6]	
	Esters TGAI	No		Reserved[6]	
83-3 - Teratogenicity (2 Species)					
- Rat	Acid TGAI	No		Yes	15 Months
	Amine TGAI	No		Yes	15 Months
	Esters TGAI	No		Yes	15 Months
- Rabbit	Acid TGAI	No		Yes	15 Months
	Amine TGAI	No		Yes	15 Months
	Esters TGAI	No		Yes	15 Months

Table A
Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds[1] (cont'd)

Data Requirement	Test Substance	Does EPA Have Data To Safety This Requirement	Bibliographic Citation	Must Additional Data Be Submitted	Timeframe for Submission
§158.340 Toxicology					
83-4 - Reproduction - Rat (2-Generation)	Acid TGAI	Yes	40257503	No	
	Amine TGAI	No		Reserved[6]	
	Esters TGAI	No		Reserved[6]	
Mutagenicity Testing					
84-2 - Gene Mutation	Acid TGAI	Partially	40257504 40257505	Yes[8]	9 Months
	Amine TGAI	No		Yes	9 Months
	Esters TGAI	No		Yes	9 Months
84-2 - Structural Chromosomal Aberration	Acid TGAI	Yes	40257506	No	
	Amine TGAI	No		Yes	12 Months
	Esters TGAI	No		Yes	12 Months
84-2 - Other Mechanisms of Mutagenicity	Acid TGAI	Yes	40257507	No	
	Amine TGAI	No		Yes	12 Months
	Esters TGAI	No		Yes	12 Months
Special Testing					
85-1 - General Metabolism	Acid PAI or PAIRA	No		Yes	24 Months
	Amine PAI or PAIRA	No		Yes	24 Months
	Esters PAI or PAIRA	No		Yes	24 Months
85-X - Neurotoxicity (Dermal)	Acid TGAI	No		Reserved[9]	
	Amine TGAI	No		Reserved[9]	
	Esters TGAI	No		Reserved[9]	

Table A

Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds1/ (cont'd)

158.340 Toxicology Footnotes

1/Requirements apply to 2,4-DB Acid as well as to the sodium salt, dimethylamine, 2-butoxyethyl ester, butyl ester and isooctyl ester forms, where [x] refers to the substituted salt, amine or ester.

2/This test is required only for compounds which are organophosphate inhibitors of cholinesterase, or related to such inhibitors or metabolites of such inhibitors. 2,4-DB compounds are not organophosphates, therefore, a study is not required.

3/This requirement is waived for 2,4-DB Acid/sodium salt based on the submission of an acceptable chronic feeding study in the rat.

4/This study is not required for the registered use patterns.

5/Since an acute neurotoxicity study is not required, this study is not required.

6/This study will be required for the amine and esters if basic studies show significant toxicology difference from the 2,4-DB Acid/sodium salt, or will be required if residues of the amine or esters appear on the raw agricultural commodities.

7/Either a new study is required or the mouse oncogenicity study on file must be upgraded to acceptable by submission of historial control data on tumor incidences (bronchiolar adenomas and carcinomas, as well as hepatocelluar carcinomas) from males of this strain of mice at the testing facility and justification that 750 ppm in the Maximum Tolerated Dose in female mice of this strain.

8/An acceptable CHO/HGPRT study without metabolic activation is required for 2,4-DB Acid.

9/A special neurotoxicity study for 2,4-DB compounds is reserved pending the outcome of the 2,4-D neurotoxicity study.

Table A
Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds[1]

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.390 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A	No		No[2]	
132-2 - Soil Dissipation	TEP	A	No		No[2]	
133-3 - Dermal Exposure	TEP	A	No		No[2]	
133-4 - Inhalation Exposure	TEP	A	No		No[2]	
§158.440 Spray Drift						
201-1 - Droplet Size	TEP	A	No		Yes[3]	6 Months
201-2 - Drift Field	TEP	A	No		Yes[3]	6 Months

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[1] Requirements apply to 2,4-DB Acid as well as to the sodium salt, dimethylamine, 2-butoxyethyl ester, butyl ester and isooctyl ester forms, where [x] refers to the substituted salt, amine or ester.

[2] Reentry data requirements are not being imposed under this Standard. Although 2,4-DB [x] products are registered for use on crops whose production and/or harvest would require human tasks characterized by a likelihood of dermal and inhalation exposure, time of application coupled with dissipation limits the exposure of workers reentering area of application. In addition, 2,4-DB [x] does not meet the toxicity requirements for §158.340.

[3] Spray drift data are being required under this Standard because 2,4-DB [x] meets the phytotoxicity requirement §158.440. The droplet spectrum study is to be performed to reflect the nozzle and other equipment types to be used in the application of 2,4-DB [x] to crops. The spray drift field evaluation to be performed to reflect the application equipment, use pattern, and typical locations of use, which includes different weather factors, in the application of 2,4-DB [x] for these uses.

Table A
Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds[1]

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.490 Wildlife and Aquatic Organisms						
Avian and Mammalian Testing						
71-1 - Acute Avian Oral Toxicity	TGAI	A	No		Yes[2]	9 Months
71-2 - Avian Subacute Dietary Toxicity						
- Upland Game Bird and Waterfowl	TGAI	A	Partially	00022923	Yes[3]	9 Months
71-3 - Wild Mammal Toxicity	TGAI		No		No[4]	
71-4 - Avian Reproduction	TGAI		No		No[4]	
71-5 - Simulated and Actual Field Testing						
- Mammals and Birds	TEP		No		No[4]	
Aquatic Organisms Testing						
72-1 - Freshwater Fish Toxicity						
- Warmwater and Coldwater	TGAI	A	Partially	40094602 40762601 40762602	Yes[5]	9 Months
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A	No		Yes	9 Months

Table A

Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds[1] (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.490 Wildlife and Aquatic Organisms						
Aquatic Organisms Testing (cont'd)						
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI		No		No[4]	
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life Cycle	TGAI	A	No		Reserved[6]	
72-5 - Fish Life Cycle	TGAI	A	No		Reserved[6]	
72-6 - Aquatic Organism Accumulation	TGAI, PAI, or Degradation Product	A	No		Reserved[6]	
72-7 - Simulated and Actual Field Testing						
- Aquatic Organisms	TEP	A	No		Reserved[6]	

1/Requirements apply to 2,4-DB Acid as well as to the sodium salt, dimethylamine, 2-butoxyethyl ester, butyl ester and isooctyl ester forms, where [x] refers to the substituted salt, amine or ester.

2/Requirement applies to 2,4-DB Acid. Testing is to be conducted with bobwhite quail. Data for 2,4-DB[x] compounds are reserved pending results of Avian Subacute Dietary Toxicity Studies.

3/The Agency has acceptable data for 2,4-DB Acid and 2,4-DB Sodium Salt. Data must be submitted for the amine and esters. Testing is to be conducted with bobwhite quail.

4/Data are not required to support current registered uses or are otherwise not applicable to this standard.

5/The Agency has acceptable data for 2,4-DB Acid and 2,4-DB Sodium Salt. Data must be submitted for the amine and esters.

6/Reserved pending results of the acute and environmental fate studies.

Table A

Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds[1]

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.540 Plant Protection						
121-1 - Target Area Phytotoxicity	TEP		No		No[2]	
Nontarget Area Phytotoxicity						
TIER I						
122-1 - Seed Germination/Seedling Emergence	TGAI		No		No[3]	
122-1 - Vegetative Vigor	TGAI		No		No[3]	
122-2 - Aquatic Plant Growth	TGAI		No		No[3]	
TIER II						
123-1 - Seed Germination/Seedling Emergence	TGAI	A	No		Yes	9 Months
123-1 - Vegetative Vigor	TGAI	A	No		Yes	9 Months
123-2 - Aquatic Plant Growth	TGAI	A	No		Yes[4]	9 Months
TIER II						
124-1 - Terrestrial Field	TEP		No		Reserved[5]	
124-1 - Aquatic Field	TEP		No		Reserved[5]	

Table A

Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds (Cont'd)

§158.540 Plant Protection Footnotes

1/Requirements apply to 2,4-DB Acid as well as to the sodium, dimethylamine, 2-butoxyethyl ester, butyl ester and isooctyl ester forms, where [x] refers to the substituted salt, amine or ester.
2/Data not required to support current registered uses or are otherwise not applicable to this standard.
3/Data are avaiable in the open literature on the phytotoxicity of the phenoxys to broadleaf plants; therefore, testing should be conducted at the Tier II level to establish EC_{50} values.
4/Data on the algae *Selenastrum capricornutum* is required.
5/Reserved pending results of Tier II.

Table A

Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds[1]

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.590 Nontarget Insect						
Nontarget Insect Testing - Pollinators						
141-1 - Honey Bee Acute Contact Toxicity	TGAI	A	Partially	00018842	Yes[2]	9 Months
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	A	No		Reserved[3]	
141-4 - Honey Bee Subacute Feeding Study					Reserved[4]	
141-5 - Field Testing for Pollinators	TEP	A	No		Reserved[3]	
Nontarget Insect Testing - Aquatic Insects						
142-1 - Acute Toxicity to Aquatic Insects					Reserved[5]	
142-2 - Aquatic Insect Life Cycle Study					Reserved[5]	
142-3 - Simulated or Actual Field Testing for Aquatic Insects					Reserved[5]	

Table A
Generic Data Requirements for 2,4-DB Acid and 2,4-DB[x] Compounds[1/] (cont'd)

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.590 Nontarget Insect						
Nontarget Insect Testing - Aquatic Insects (cont'd)						
143-1 - Nontarget Insect thru Testing - Predators 143-3 - and Parasites					Reserved[4/]	

1/Requirements apply to 2,4-DB Acid as well as to the sodium, dimethylamine, 2-butoxyethyl ester, butyl ester and isooctyl ester forms, where [x] refers to the substituted salt, amine or ester.

2/The Agency has acceptable data for 2,4-DB dimethylamine. Data must be submitted for 2,4-DB butoxyethyl ester and 2,4-DB isooctyl ester.

3/As data from the acute contact test indicate low toxicity for 2,4-DB dimethylamine; no further testing is required for this form of 2,4-DB. Reserved for 2,4-DB butoxyethyl ester and 2,4-DB isooctyl ester pending evaluation of data from acute contact test.

4/Reserved pending development of test methodology.

5/Reserved pending Agency decision as to whether the data requirement should be established.

Table B

Product-Specific Data Requirements for Manufacturing-Use Products Containing 2,4-DB Acid and 2,4-DB[x] Compounds[1]

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation[2]	Must Additional Data Be Submitted?	Timeframe for Submission
§158.190 Product Chemistry					
Product Identity					
61-1 - Product Identity and Disclosure of Ingredients	MP	No	N/A	Yes[3]	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No	N/A	Yes[4]	6 Months
61-3 - Discussion of Formation of Impurities	MP	No	N/A	Yes[5]	6 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis	MP	No	N/A	Yes[6]	12 Months
62-2 - Certification of Limits	MP	No	N/A	Yes[7]	12 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	No	N/A	Yes[8]	12 Months

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing 2,4-DB Acid and 2,4-DB[x] Compounds[1] (cont'd)

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation[2]	Must Additional Data Be Submitted?	Timeframe for Submission
§158.190 Product Chemistry					
Physical and Chemical Characteristics					
63-2 - Color	MP	No	N/A	Yes[9]	6 Months
63-3 - Physical State	MP	No	N/A	Yes[9]	6 Months
63-4 - Odor	MP	No	N/A	Yes[9]	6 Months
63-7 - Density, Bulk Density, or Specific Gravity	MP	No	N/A	Yes[9]	6 Months
63-12 - pH	MP	No	N/A	Yes[9,10]	6 Months
63-14 - Oxidizing or Reducing Action	MP	No	N/A	Yes[9,11]	6 Months
63-15 - Flammability	MP	No	N/A	Yes[9,12]	6 Months
63-16 - Explodability	MP	No	N/A	Yes[9,13]	6 Months
63-17 - Storage Stability	MP	No	N/A	Yes[9]	15 Months
63-18 - Viscosity	MP	No	N/A	Yes[9,14]	6 Months
63-19 - Miscibility	MP	No	N/A	Yes[9,15]	6 Months
63-20 - Corrosion Characteristics	MP	No	N/A	Yes[9]	15 Months

Table B

Product-Specific Data Requirements for Manufacturing-Use Products Containing 2,4-DB Acid and 2,4-DB[x] Compounds1/ (cont'd)

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation2/	Must Additional Data Be Submitted?	Timeframe for Submission
§158.190 Product Chemistry					
Other Requirements					
64-1 - Submittal of Samples	N/A	N/A	N/A	No	

1/Requirements apply to 2,4-DB Acid as well as to the sodium salt, dimethylamine, 2-butoxyethyl ester, butyl ester and isooctyl ester forms, where [x] refers to the substituted salt, amine or ester.

2/Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

3/The chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredients, the following must also be provided: The product's common and trade names; the molecular, structural, or empirical formulas; the molecular weight or range; and any experimental or internally assigned company code numbers.

4/Complete information must be provided regarding the nature of the process (batch or continuous); the relative amounts of beginning materials and the order in which they are added; the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product; reaction conditions; the duration of each step of the process; purification procedures and quality control measures. In addition, the name and address of the manufacture producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials. In order to assess the potential for contamination with halogenated dibenzo-p-dioxins and dibenzofurans, the description of the manufacturing process must also include the range of temperature conditions, pressure, and pH at each reaction step. Refer to the data requirements set forth in the Agency's June 1987 Data Call-In Notice for analytical chemistry data on halognated dibenzo-p-dioxins/dibenzofurans in 2,4-DB. These data are due as specified in the Data Call-In Notice.

5/A detailed discussion of all impurities that are or may be present at 0.1% based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. This discussion must also address the possible formation of dibenzo-p-dioxins and dibenzofurans for all products and N-nitrosamines for amines. Refer to the data requirements set forth in the Agency's June 1987 Data Call-In Notice for anaytical chemistry data on halogenated dibenzo-p-dioxins/dibenzofurans in 2,4-DB. These data are due as specified in the Data Call-In Notice.

Table B
Product-Specific Data Requirements for Manufacturing-Use Products Containing 2,4-DB Acid and 2,4-DB[x] Compounds[1]/ (cont'd)

§158.190 Product Chemistry Footnote (cont'd)

6/Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete validation data (accuracy and precision) must be submitted for each analytical method used. All nitrosamines must be identified and quantified in six samples of each amine; two samples must be analyzed shortly after production, 3 months after production, and 6 months after production. A method sensitive to 1 ppm of N-nitroso contaminants must be used. An upper limit must be provided (and certified) for all nitrosamines found. Certifications should be submitted on EPA Form 8570-4 (Rev. 2-85).

7/Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at 0.1% (w/w) and each "toxicologically significant" impurity present at < 0.1% (w/w) must be provided and certified. Also, an explanation of how each certified limit was established must provided (e.g., sample analyses using validated analytical procedures, quantitative estimates based on amounts of ingredients used, etc.) Limits for impurities not associated with the active ingredient need to be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certification must be submitted on EPA Form 8570-4 (Rev. 2-85).

8/Analytical methods must be provided to determine the active ingredient, and each "toxicologically significant" impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

9/Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

10/Data required if test substance is dispersible in water.

11/Data required if product contains oxidizing or reducing agents.

12/Data required if product contains combustible liquids.

13/Data required if product is potentially explosive.

14/Data required if product is a liquid.

15/Data required if product is a liquid and is to be diluted with petroleum solvents.

Table B
Product Specific Data Requirements for Manufacturing-Use Products Containging 2,4-DB Acid and 2,4-DB[x] Compounds[1]

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
§158.340 Toxicology					
Acute Testing					
81-1 - Acute Oral Toxicity - Rat	MP	Partially	00092159 00128854	Yes[2]	9 Months
81-2 - Acute Dermal Toxicity	MP	Partially	00128854	Yes[2]	9 Months
81-3 - Acute Inhalation Toxicity - Rat	MP	No		Yes	9 Months
81-4 - Primary Eye Irritation - Rabbit	MP	Partially	00092160	Yes[2]	9 months
81-5 - Primary Dermal Irritation - Rabbit	MP	Partially	00128854	Yes[2]	9 months
81-6 - Dermal Sensitization Guinea Pig	MP	No		Yes	9 months

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[1] Requirements apply to 2,4-DB Acid as well as the sodium salt, dimethylamine, 2-butoxyethyl ester, butyl ester, and isooctyl ester forms, where [x] refers to the substituted salt, amine or ester.

[2] The Agency has acceptable data for 2,4-DB Acid only. Data must be submitted for the amine and ester manufacturing-use products.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40CFR 156.10(h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 156.10(h)(1)(i)

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv).

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

   b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

   c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§156.10 Labeling Requirements for Pesticides and Devices.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ****" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) *Directions for Use*--(1) *General requirements*--(i) *Adequacy and clarity of directions*. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use*. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978; amended at 53 FR 15952, May 4, 1988]

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDES

HEADING: All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

STORAGE INSTRUCTIONS: All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement:

   "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

   "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement:

> "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting
Registrations Under the 2,4-DB Standard

MRID	CITATION
00004685	Linscott, D.L. (1964) Degradation of 4-(2,4-Dichlorophenoxy)-butyric acid [4-(2,4-DB)] in plants. Journal of Agricultural and Food Chemistry 12(1):7-10. (Also in unpublished submission received Sep 16, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092090-AD)
00004701	Bache, C.A.; Hardee, D.D.; Holland, R.F.; Lisk, D.J. (1964) Absence of Phenoxyacid herbicide residues in the milk of dairy cows at high feeding levels. Journal of Dairy Science XLVII(3):298-299. (Also in unpublished submission received Sep 12, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL: 092980-O)
00004718	Hagin, R.D.; Linscott, D.L. (1965) Determination of 4-(2,4-Dichlorophenoxy)-butyric acid (2,4-DB) and 2,4-Dichlorophenoxyacetic acid (2,4-D) in forage plants. Journal of Agricultural and Food Chemistry 13(2):123-125. (Also in unpublished submission received Sep 12, 1968 under 8F0676; submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092980-AJ)
00009181	Atkins, E.L., Jr.; Anderson, L.D.; Greywood, E.A. (1969) Effect of Pesticides on Apiculture: Project No. 1499. (Unpublished study received Jul 29, 1976 under 352-342; prepared by Univ. of California--Riverside, Dept. of Entomology, submitted by E.I. du Pont de Nemours & Co., Wilmington, Del.; CDL:224800-C)
00018284	E.I. du Pont de Nemours & Company (1972) Data Supporting the Use of Lorox Linuron Weed Killer plus Butyrac 175 as a Tank Mixture as a Directed Postemergence Spray To Control Certain Weeds in Soybeans. Summary of studies 002892-B and 002892-C. (Unpublished study received Jul 16, 1973 under 352-270; CDL:002892-A)
00022923	Hill, E.F.; Heath, R.G.; Spann, J.W.; et al. (1975) Lethal Dietary Toxicities of Environmental Pollutants to Birds: Special Scientific Report--Wildlife No. 191. (U.S. Dept. of the Interior, Fish and Wildlife Service, Patuxent Wildlife Research Center; unpublished report)
00027041	Bache, C.A.; Hardee, D.D.; Holland, R.F.; et al. (19??) Absence of Phenoxyacid herbicide residues in the milk of dairy cows at high feeding levels. Journal of Dairy Science ? (?):298-299. (Also in unpublished submission received Jan 2, 1980 under 2217-641; submitted by PBI-Gordon Corp., Kansas City, Kans.; CDL:241575-T)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the 2,4-DB Standard

MRID	CITATION
00037371	Shea, D.; Stanovick, R.P.; Parochetti, J.; et al. (1973) Final Report: Analysis for 2,4 DB Residues in Soybeans (Mature Bean and Forage). (Unpublished study including letter dated Mar 16, 1973 from M.D. Parkins to Richard J. Otten, received Jun 7, 1973 under 264-164; prepared by Environmental Sciences Corp. and others, submitted by Union Carbide Agricultural Products Co., Ambler, Pa.; CDL:002131-B)
00046125	Yip, G. (1964) Herbicides and plant growth regulators: Determination of herbicides in oils. Journal of the Association of Official Analytical Chemists 47(6):1116-1119. (Also in unpublished submission received on unknown date under 6F0459; submitted by U.S. Dept. of Agriculture, Agricultural Research Service, unknown location; CDL:098165-I)
00061012	National Agricultural Chemical Association (1967?) Summary of Residues. (Compilation; unpublished study received May 15, 1967 under 8F0670; CDL:091172-AN)
00087925	Mobay Chemical Corporation (1978) Sencor Residue Chemistry on Soybeans: Supplement No. 5. (Compilation; unpublished study received Dec 16, 1981 under 3125-277; CDL:246510-A)
00092159	Holsing, G.C. (1969) Final Report: Acute Oral Administration--Rats: Project No. 656-105. (Unpublished study received Dec 16, 1970 under 1F1089; prepared by TRW, Inc., submitted by Rhodia, Inc., New Brunswick, N.J.; CDL:090849-B)
00092160	Holsing, G.C. (1969) Final Report: Acute Eye Irritation--Rabbits: Project No. 656-108. (Unpublished study received Dec 16, 1970 under 1F1089; prepared by TRW, Inc., submitted by Rhodia, Inc., New Brunswick, N.J.; CDL:090849-C)
00102943	Interregional Research Project No. 4 (1978) Petition for the Use of 2,4-DB on Spearmint and Peppermint. (Unpublished study received May 24, 1982 under 2E2694; CDL:070875-A)
00104739	Holsing, G.C.; Kundzin, M.; Voelker, R.W., Jr. (1969) Final Report: Three-month Dietary Administration--Albino Rats: Project No. 656-109. (Unpublished study received Dec 16, 1970 under 1F1089; prepared by TRW, Inc., submitted by Rhodia, Inc., New Brunswick, N.J.; CDL:090849-I)

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the 2,4-DB Standard

MRID	CITATION
00106319	Uniroyal Chemical (1979) Alanap-L: Label Amendment for Tank Mix with Butyrac 200 or Butoxone Overtop of Soybeans. (Compilation; unpublished study received Mar 8, 1979 under 400-49; CDL: 237772-A)
00115135	Uniroyal Chemical (1982) [Study: RESCUE Residue on Soybeans]. (Compilation; unpublished study received Sep 15, 1982 under 400-166; CDL:248367-F)
00116018	Rhodia, Inc. (1972) [Study: 4(2,4-DB) Residues in Selected Crops]. (Compilation; unpublished study received May 31, 1972 under 1F1089; CDL:090848-A)
00128854	Myers, R.; Coleman, J.; Bellich, N.; et al. (1982) Technical 2,4-DB Acid: Acute Toxicity and Irritancy Studies: Project Report 45-188. (Unpublished study received Apr 19, 1983 under 264-273; submitted by Union Carbide Agricultural Products Co., Inc., Research Triangle Park, NC; CDL:250433-A)
00132034	Interregional Research Project No. 4 (1980) The Results of Tests on the Amount of 2,4-DB Residues Remaining in or on Oats, Including a Description of the Analytical Method Used. (Compilation; unpublished study received Oct 13, 1983 under 4E2982; CDL: 072030-A)
00161196	Rhodia, Inc., Chipman Div. (1974) The Results of Tests on the Amount of 4-(2,4-dichlorophenoxy Butyric Acid (2,4-DB) Remaining in or on Peppermint Including A Description of the Analytical Method Used. Unpublished compilation. 63 p.
40094602	Johnson, W.; Finley, M. (1980) Handbook of Acute Toxicity of Chemicals to Fish and Aquatic Invertebrates: Resource Publication 137. US Fish and Wildlife Service, Washington, D.C. 106 p.
40257501	Mackenzie, K. (1987) Lifetime Dietary Combined Chronic Toxicity and Oncogenicity Study in Albino Rats with 2,4-DB: Laboratory Project No. HLA 6158-103. Unpublished study prepared by Hazleton Laboratories America, Inc. 3095 p.
40257503	Bottomley, A.; Bowman, A.; Offer, J.; et al. (1986) 2,4-DB--Effect on Two Generations of the Rats: Laboratory Project ID: UNC/138-R. Unpublished study prepared by Huntingdon Research Centre Ltd. 549 p.

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION STANDARD BIBLIOGRAPHY
Citations Considered to be Part of the Data Base Supporting Registrations Under the 2,4-DB Standard

MRID	CITATION
40257504	Jagannath, D. (1987) Mutagenicity Test on 2,4-DB Technical 98.03% ... in the Ames Salmonella/Microsome Reverse Mutation Assay: HLA Study No.: 9360-0-401TR. Unpublished study prepared by Hazleton Laboratories America, Inc. 32 p.
40257505	Young, R. (1987) Mutagenicity Test on 2,4-DB, Technical ... in the CHO/HGPRT Forward Mutation Assay: HLA Study No.: 9360-0-435. Unpublished study prepared by Hazleton Laboratories America, Inc. 35 p.
40257506	Ivett, J. (1987) Mutagenicity Test on 2,4-DB Tech 98.03% in an in vitro Cytogenic Assay Measuring Chromosomal Aberration Frequencies in Chinese Hamster Ovary (CHO) Cells: HLA Study No. 9360-0-437. Unpublished study prepared by Hazleton Laboratories America, Inc. 30 p.
40257507	Cifone, M. (1987) Mutagenicity Test on 2,4-DB Technical, 98.03% in the Rat Primary Hepatocyte Unscheduled DNA Synthesis Assay: HLA Study No. 9360-0-447. Unpublished study prepared by Hazleton Laboratories America, Inc. 24 p.
40762601	McCann, J. (1976) Biological Report of Analysis of Amchem Technical 2,4-DB: Rainbow Trout (salmo gairdneri): Static Jar Test 928. Unpublished study prepared by Terrestrial and Aquatic Biology Laboratory. 1 p.
40762602	McCann, J. (1976) Biological Report of Analysis of Amchem Technical 2,4-DB: Bluegill (lepomis macrichirus): Static Jar Test 938. Unpublished study prepared by Terrestrial and Aquatic Biology Laboratory. 1 p.

IV FORMS APPENDICES

EPA Form 8580-1

OMB Approval No. 2070-0057
Expires 11/30/89

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	**EPA REGISTRATION NO**
PRODUCT NAME	
APPLICANT'S NAME	**DATE GUIDANCE DOCUMENT ISSUED**

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements.

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	**SIGNATURE**	**DATE**

EPA Form 8580-6

OMB Approval No. 2070-0057
Expires 11/30/89

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	**GUIDANCE DOCUMENT DATE** **ACTIVE INGREDIENT**

NAME OF FIRM	**EPA COMPANY NUMBER**

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	**DATE OF OFFER**

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	**SIGNATURE**	**DATE**

OMB Approval No. 2070-0057
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.______________________________ Date__________________________________

Guidance Document for____

			I am complying with data requirements by		
Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	(For EPA Use Only) MRID Numbers Assigned
Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

EPA Form 8580-4

OMB Approval No. 2070-0057
Expires 11/30/89

PRODUCT SPECIFIC DATA REPORT (cont'd)

EPA Reg. No.____________________ Date____________________

Guidance Document for____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) MRID Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
Subpart C PRODUCT CHEMISTRY (cont'd)					
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.340 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization,				
81-7	Acute Delayed neurotoxicity, hen				

EPA Form 8580-4 (cont'd)

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________________
Registrant's Name and Address: ____
____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _________ concerning a requirement for submission of "generic" data on the active ingredient _________________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated ____________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are _________ and their registration number(s) is/are __________.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ____________________________________
(Signature

Dated: ______________________ ____________________________________
(Typed)2

EPA Form 8570-27